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EXAMINER	
MALLARI, PATRICIA C	
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3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,364	JUST ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41 and 54-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21,24,25 and 28* is/are allowed.

6)☒ Claim(s) *1-20,22,23,26,27,29-41 and 54-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/10/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims.

Information Disclosure Statement

The information disclosure statement filed 2/6/07 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because each page of the list does not include a column that provides a space next to each document to be considered for the examiner's initials or a heading that clearly indicates that the list is a information disclosure statement. See 37 CFR 1.98(a) (1)(ii) and (iii). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

The disclosure is objected to because of the following informalities:

On line 2 of the first paragraph of the specification under "Related Applications", "2002," should be replaced with "2002, now US Patent No. 6,988,992".

Appropriate correction is required.

Claim Objections

Claim 27 is objected to because of the following informalities:

On line 3 of claim 27, "cuffed" should be replaced with "cuff". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7, 65, 67, and 69 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 7 recites, "the sleeve . . . resides securely against a desired portion of the limb of the patient". Claims 65, 67, and 69 each recites, "one rib projects inwardly toward skin of the limb of the patient inside the wrapped cuff". The human body and parts thereof are non-statutory subject matter and cannot be positively claimed. For example, changing "resides" on line 4 of claim 7 to "is configured to reside" may overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6-8, 13, 14, 17, 19, 20, 27, 29-35, 37, 39-41, 65, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,979,953 to Spence. Spence teaches an inflatable blood pressure cuff assembly comprising an inflatable elongate cuff member 13, 14 having opposing long edges and opposing short edge portions with an inflatable fluid chamber 12 therein (see entire document, especially figs. 2 & 4; col. 3, lines 19-32 of Spence). A resilient sleeve 15, 16 is attached to a respective one of the opposing short edge portions of the cuff member (see entire document, especially figs. 1, 3, & 4; col. 3, lines 41-46 of Spence). The sleeve comprises at least one substantially longitudinally extending rib support member 17, 42 and the rib is configured to inhibit the sleeve from rolling up and/or down the limb of the patient (see entire document, especially fig. 1; col. 3, line 54-col. 4, line 2 of Spence), wherein the stiffness provided by the stitching and/or the added material of strip 17, 42 would serve to prevent such rolling at the edges of the sleeve. The sleeve's circumference may be adjusted to snugly fit the arm of a patient using strap 41 and strip 40 (see entire document, especially fig. 1; co. 3, lines 47-53 of Spence) and the sleeve may be made of nylon (see entire document, especially col. 4, lines 1-4 of Spence), wherein nylon is an elastic fiber, such that the sleeve has a body sized and configured such that the sleeve is capable of expanding elastically to snugly and substantially conformably fit on a limb of the patient prior to inflation of the cuff member.

As to the language "blood pressure" in the preamble of claim 1, the applicants should note that this is merely an "intended use" designation, wherein the apparatus of Spence is fully capable of use to determine blood pressure.

Regarding claims 2 and 35, the at least one rib support member has an elongate flexible body 17 configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 1 & 3 of Spence).

Regarding claims 4 and 37, the at least one rib support member is a plurality of laterally spaced apart rib support members configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially fig. 1 of Spence).

Regarding claims 5 and 8, the sleeve is air permeable and comprises a fabric that includes stretch fibers (see entire document, especially col. 4, lines 1-4 of Spence), wherein nylon fabric is air permeable (see, for example, claim 1 of US Patent No. 3,892,425, claim 7 of US Patent No. 5,007,112, or the abstract of US Patent No. 4,274,158 for a teaching of nylon fabric as being air permeable). With further regard to claim 8, the sleeve comprises nylon fibers, since it is made of a nylon fabric.

Regarding claim 6, the sleeve has a closed perimeter configuration, when strap 41 and strip 40 are attached, defining an aperture extending in the axial direction, wherein the sleeve aperture is sized and configured to stretch (due to the use of elastic fabrics) during use (see entire document, especially fig. 1; col. 3, lines 47-52 of Spence). As to the language "to receive a limb of a patient" on line 3 of claim 6, the

applicants should note that the limitation is "intended use" language, which cannot be relied upon to define over the prior art, since Spence teaches all of the claimed structural limitations and their recited relationships. The sleeve of Spence is certainly capable of stretching order to receive a limb, as claimed.

Regarding claim 7, the sleeve is capable of at least two configuration having different widths, due to the cooperation of the Velcro strip and strap, wherein, during periods of non-use, the sleeve may be placed in a configuration such that the width or diameter of the opening of the sleeve is narrower than that required when the sleeve is placed on the limb of a patient. The sleeve is capable of a second width or configuration, wherein the width or diameter of the opening of the sleeve is wider such that the sleeve is substantially conformable to and resides securely against a desired portion of the limb of the patient with sufficient compressive force so that it is able to maintain its desired longitudinal position to thereby inhibit slippage during use.

Regarding claim 13, the sleeve may have a frustoconical shape, or a shape resembling the frustum of a cone (see entire document, especially fig. 1 of Spence), wherein, when the sleeve is applied to the patient's arm and secured, the sleeve may take such a shape since the diameter of the arm becomes progressively smaller in a direction, for example, from the bicep towards the elbow.

Regarding claim 14, the cuff member is bladderless (see entire document, especially figs. 3 & 4 of Spence).

Regarding claims 17, 19, 20, and 66, in position, the sleeve is configured to define a first closed member before the cuff is wrapped over the sleeve, wherein the

sleeve is a closed member since all the edges are sealed such that the interior or the sleeve is enclosed. The cuff member defined a second closed member after the cuff member is wrapped over the sleeve, wherein, when the sleeve and cuff member are wrapped on a patient's limb the connection of the two ends of the cuff member, effected by the cuff members' attachment to the sleeve and the two attached ends of the sleeve, form a closed member of the cuff member, and at least a portion of the cuff member is wrapped over the sleeve (see entire document, especially figs. 1 & 4 of Spence). With further regard to claim 17, the sleeve comprises a sensor chamber 27, 28, wherein the term "sensor" is merely an indication of "intended use" and the chamber 27, 28 may be used to connect to a sensor or alternatively is capable of receiving a sensor (see entire document, especially fig. 1of Spence). Alternatively, the space between one sleeve wall 15, 16 and the cuff member may be considered a sensor chamber, wherein the space is capable of containing a sensor therein (see entire document, especially fig. 3, 4 of Spence). With further regard to claim 19, the sleeve comprises upper and lower edge portions, wherein the designation of upper and lower depends on the way in which the sleeve is placed or held. The sensor chamber 27, 28 (or space between the wall 15, 16 of the sleeve and the cuff member) is proximate an edge portion which may be considered the lower edge portion. With further regard to claim 20, the lower edge portion of the sensor chamber 27, 28 is seamless, where, again, the designation lower depends on the orientation of the device as a whole, and the tubing of the chamber itself appears seamless.

Regarding claims 27, 29, 39, and 40, the sleeve is attached to the cuff member in both a fixedly attached and a releasably detachable manner, wherein the sleeve and cuff member are fixedly attached by stitches, but the sleeve may be released from its attachment to the cuff member by undoing or destroying the stitches (see entire document, especially figs. 1, 3 & 4; col. 3, line 40-col. 4, line 2 of Spence), and is configured to reside against the limb of the patient wrapped thereabout during use, wherein the when the sleeve and cuff are wrapped in place on the patient, the cuff is at least wrapped about one side of the sleeve.

Regarding claims 30 and 41, the sleeve has opposing first and second short end portions, wherein the first end portion is configured to releasably attach to the second short end portion of the sleeve via the Velcro strip and strap (see entire document, especially fig. 1 of Spence).

Regarding claim 31, the cuff member and sleeve are configured to accommodate both the left and right arm of a patient.

Regarding claims 32 and 33, the assembly is configured to be used for ambulatory blood pressure measurements or stress test blood pressure measurements. Applicants should note that "ambulatory blood pressure" and "stress test blood pressure" is merely "intended use" language, which cannot be relied upon to define over the prior art, since Spence teaches all of the claimed structural limitations and their recited relationships.

Regarding claims 34, 35, 37, 39, 40, and 41, the short edge portions of the cuff member are configured to wrap about a body portion of a user and connect to each

other, particularly in that they are connected to the sleeve edge portions, which connected to each other via the Velcro strip and strap and rib 42 (see entire document, especially figs. 1, 3, & 4; col. 3, lines 46-53 of Spence). The sleeve is configured to reside under the wrapped cuff member when the sleeve and cuff member are placed on the patient's arm, wherein at least a portion of the sleeve resides under the cuff member during such placement.

Regarding claim 65, the at least one rib projects inwardly, such that it projects toward the skin of the patient, when the sleeve and cuff are applied to the patient's limb (see entire document, especially figs. 3 & 4 of Spence).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-8, 13, 14, 17-19, 22, 23, 27, 29-36, 39-41, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,838,276 to Nagai et al. in view of Spence. Nagai teaches an inflatable blood pressure cuff assembly comprising an inflatable cuff member having an inflatable fluid chamber therein (inflatable bladder) and a resilient sleeve 14, 16, the sleeve comprising at least one substantially longitudinally extending rib support member 32, wherein the rib is configured to inhibit the sleeve from rolling up and/or down the limb of the patient (see

entire document, especially figs. 1-3; col. 2, lines 1-19 and lines 52-64 of Nagai). Nagai is silent as to the construction of the cuff member with respect to the sleeve and as to the material from which the sleeve is made

However, Spence teaches an inflatable tourniquet cuff assembly, wherein a tourniquet is known to be used for blood pressure measurement, comprising an inflatable elongate cuff member 13, 14 having opposing long edges and opposing short edge portions with an inflatable fluid chamber 12 therein (see entire document, especially figs. 2 & 4; col. 3, lines 19-32 of Spence). A resilient sleeve 15, 16 is attached to a respective one of the opposing short edge portions of the cuff member (see entire document, especially figs. 1, 3, & 4; col. 3, lines 41-46 of Spence). The sleeve's circumference may be adjusted to snugly fit the arm of a patient using strap 41 and strip 40 (see entire document, especially fig. 1; co. 3, lines 47-53 of Spence) and the sleeve may be made of nylon (see entire document, especially col. 4, lines 1-4 of Spence), wherein nylon is an elastic fiber, such that the sleeve has a body sized and configured such that the sleeve is capable of expanding elastically to snugly and substantially conformably fit on a limb of the patient prior to inflation of the cuff member. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the construction of the cuff member with respect to the sleeve of Spence as that of Nagai, since Nagai teaches an inflatable cuff member within a sleeve, and Spence describes appropriate construction of such a cuff member within a sleeve. It would similarly have been obvious to one of ordinary skill in the art at the time of invention to use the material of the sleeve of Spence as that of Nagai, since Nagai

teaches a pressure cuff having a sleeve, and Spence describes appropriate material for such a sleeve.

Regarding claims 2 and 35, the at least one rib support member has an elongate flexible body configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user, wherein every substance has at least some small degree of flexibility (see entire document, especially figs. 1 and 2 of Nagai).

Regarding claims 3 and 36, the sleeve comprises at least one rib channel 33 sized and configured to hold the at least one rib support member therein (see entire document, especially figs. 1 & 2; col. 2, lines 20-25 of Nagai).

Regarding claims 5 and 8, the sleeve is air permeable and comprises a fabric that includes stretch fibers (see entire document, especially col. 4, lines 1-4 of Spence), wherein nylon fabric is air permeable (see, for example, claim 1 of US Patent No. 3,892,425, claim 7 of US Patent No. 5,007,112, or the abstract of US Patent No. 4,274,158 for a teaching of nylon fabric as being air permeable). With further regard to claim 8, the sleeve comprises nylon fibers, since it is made of a nylon fabric.

Regarding claim 6, the sleeve has a closed perimeter configuration, when the sleeve and cuff member are applied to an arm as shown in figure 6 of Nagai and portions 24 and 26 are connected, defining an aperture extending in the axial direction, wherein the sleeve aperture is sized and configured to stretch (due to the use of elastic fabrics) during use (see entire document, especially fig. 1; col. 3, lines 47-52 of Spence). As to the language "to receive a limb of a patient" on line 3 of claim 6, the applicants should note that the limitation is "intended use" language, which cannot be

relied upon to define over the prior art, since Nagai, as modified, teaches all of the claimed structural limitations and their recited relationships. The sleeve of Nagai, as modified, is certainly capable of stretching order to receive a limb, as claimed.

Regarding claim 7, the sleeve is capable of at least two configuration having different widths, due to the cooperation of the connecting portions 24, 26, wherein, during periods of non-use, the sleeve may be placed in a configuration such that the width or diameter of the opening of the sleeve is narrower than that required when the sleeve is placed on the limb of a patient. The sleeve is capable of a second width or configuration, wherein the width or diameter of the opening of the sleeve is wider such that the sleeve is substantially conformable to and resides securely against a desired portion of the limb of the patient with sufficient compressive force so that it is able to maintain its desired longitudinal position to thereby inhibit slippage during use.

Regarding claim 13, the sleeve may have a frustoconical shape, or a shape resembling the frustum of a cone (see entire document, especially fig. 6 of Nagai), wherein, when the sleeve is applied to the patient's arm and secured, the sleeve may take such a shape since the diameter of the arm becomes progressively smaller in a direction, for example, from the bicep towards the elbow.

Regarding claim 14, the cuff member is bladderless (see entire document, especially figs. 3 & 4 of Spence).

Regarding claims 17-19, 22, 23 and 66, in position, the sleeve is configured to define a first closed member before the cuff is wrapped over the sleeve, wherein the sleeve is a closed member since all the edges are sealed such that the interior or the

sleeve is enclosed. The cuff member defined a second closed member after the cuff member is wrapped over the sleeve, wherein, when the sleeve and cuff member are wrapped on a patient's limb the connection of the two ends of the cuff member, effected by the cuff members' attachment to the sleeve and the two attached ends of the sleeve, form a closed member of the cuff member, and at least a portion of the cuff member is wrapped over the sleeve (see entire document, especially (figs. 1, 2, and 6 of Nagai). With further regard to claim 17, the sleeve comprises a sensor chamber 18 (see entire document, especially figs. 1 & 6; col. 2, lines 52-57 of Nagai).

With further regard to claim 18, a sensor 50 is held in the sensor chamber (see entire document, especially fig. 6; col. 2, lines 52-57 of Nagai).

With further regard to claims 19, 22, and 23 the chamber 18 appears to extend from a lower edge portion of the sleeve to an upper edge portion of the sleeve (see entire document, especially fig. 1 and col. 2, lines 1-19 and fig. 4 of Spence). With further regard to claims 22 and 23, the sleeve further comprises a cable channel 22 in communication with the sensor chamber (see entire document, especially figs. 1 & 6; col. 2, lines 6-14 of Nagai). With further regard to claim 23, the sleeve cable channel is shown as being curvilinear (see entire document, especially figs. 1 & 6 of Nagai).

Regarding claims 27, 29, 39, and 40, the sleeve is attached to the cuff member in both a fixedly attached and a releasably detachable manner, wherein the sleeve and cuff member are fixedly attached by stitches, but the sleeve may be released from its attachment to the cuff member by undoing or destroying the stitches (see entire document, especially figs. 1, 3 & 4; col. 3, line 40-col. 4, line 2 of Spence), and is

configured to reside against the limb of the patient wrapped thereabout during use, wherein the when the sleeve and cuff are wrapped in place on the patient, the cuff is at least wrapped about one side of the sleeve.

Regarding claims 30 and 41, the sleeve has opposing first and second short end portions, wherein the first end portion is configured to releasably attach to the second short end portion of the sleeve via the Velcro strip and strap (see entire document, especially fig. 2 of Nagai).

Regarding claim 31, the cuff member and sleeve are configured to accommodate both the left and right arm of a patient.

Regarding claims 32 and 33, the assembly is configured to be used for ambulatory blood pressure measurements or stress test blood pressure measurements. Applicants should note that "ambulatory blood pressure" and "stress test blood pressure" is merely "intended use" language, which cannot be relied upon to define over the prior art, since Spence teaches all of the claimed structural limitations and their recited relationships.

Regarding claims 34-36, and 39- 41, the short edge portions of the cuff member are configured to wrap about a body portion of a user and connect to each other, particularly in that they are connected to the sleeve edge portions, which connected to each other via connecting portions 24, 26 (see entire document, especially figs. 1, 2, and 6 of Nagai). The sleeve is configured to reside under the wrapped cuff member when the sleeve and cuff member are placed on the patient's arm, wherein at least a portion of the sleeve resides under the cuff member during such placement.

Regarding claim 65, the at least one rib projects inwardly, such that it projects toward the skin of the patient, when the sleeve and cuff are applied to the patient's limb (see entire document, especially figs. 3 & 4 of Spence).

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence, as applied to claims above. Spence fails to address the amount of stretch afforded by the material. However, the applicants have not disclosed that the specific amount of at least 15% elastic lateral stretch portion to provide a second configuration width solves any stated problem or is for any particular purpose. Moreover, it appears that the cuff assembly would perform equally well having any amount of stretch. Accordingly, the use of at least about 15% of elastic stretch is deemed a mere design consideration which fails to patentably distinguish over the prior art.

Regarding claim 11, the sleeve elastically stretches since it is made of an elastic material (nylon) wherein the sleeve appears capable of accommodating patients having limbs that vary in width up to at least about 150%, and wherein such stretch aids this accommodation.

Regarding claim 12, the sleeve is sized and configured to accommodate patient having limbs that vary in width between about 100-205% (see entire document, especially fig. 1 of Spence).

Claims 9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence, as applied to claims above, and further in view of US Patent No. 5,344,406 to

Spooner. Spence is silent as to whether the material is anisotropic. Spooner teaches a nylon and spandex material (see entire document, especially col. 4, lines 3-14 of Spooner). The applicants have not disclosed that the use of an anisotropic material or a material comprising spandex fibers solves any stated problem or is for any particular purpose. Moreover, it appears that the cuff assembly would perform equally well having any suitable type of elastic material. Accordingly, the use of spandex fibers or of an anisotropic material is deemed a mere design consideration which fails to patentably distinguish over the prior art, and it would have been obvious to one of ordinary skill in the art at the time of invention to use the material of Spooner as the material of Spence, as a mere matter of design choice.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spence, as applied to claims above, and further in view of the applicants' admission. Spence teaches using a cuff member that is "bladderless" rather than a cuff member comprising a pouch and inflatable bladder configured to reside therein. However, the applicants have stated on the record that the "bladderless" cuff member and the cuff member comprising a pouch and inflatable bladder are obvious variants ("sufficiently similar in design and use as to overlap in scope" on p.9 of the remarks filed 10/30/06. The previous Office action also stated that the election requirement between A and B was withdrawn in light of the applicants' admission of obviousness. The applicants did not protest or disagree with this statement in their remarks.) Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a cuff member

comprising a pouch and inflatable bladder in place of the "bladderless" cuff member of Spence, in view of the applicants' admission that these are obvious variants.

In the alternative, claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spence, as applied to claims above, and further in view of US Patent No. 4,548,249 to Slaughterbeck. Spence teaches a "bladderless" cuff member. However, Slaughterbeck teaches a cuff member within a sleeve, wherein the cuff member comprises a pouch and inflatable bladder configured to reside therein (see entire document, especially figs. 2 & 5 of Slaughterbeck; while Slaughterbeck does not explicitly address the interior bladder in figs. 2 & 5, the reference does state that the sphygmomanometer is a typical one, such that the interior bladder must be inflatable, as is the case with typical sphygmomanometers). Therefore, it would have been one of ordinary skill in the art at the time of invention to use the cuff member of Slaughterbeck as that of Spence, as it would merely be the substitution of one known cuff member for another known cuff member.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spence, in view of the applicants' admission or in view of Slaughterbeck, as applied to claim 15 above, and further in view of Spooner. Spence is silent as to the details of the material of the sleeve, other than stating that it comprises nylon. Spooner teaches a nylon and spandex material (see entire document, especially col. 4, lines 3-14 of Spooner). The applicants have not disclosed that the use a fabric comprising nylon as a major constituent and spandex as a minor constituent solves any stated problem or is for any

particular purpose. Moreover, it appears that the cuff assembly would perform equally well having any suitable type of elastic material. Accordingly, the use of a fabric comprising nylon as a major constituent and spandex as a minor constituent is deemed a mere design consideration which fails to patentably distinguish over the prior art, and it would have been obvious to one of ordinary skill in the art at the time of invention to use the material of Spooner as the material of Spence, as modified, as a mere matter of design choice.

Claims 34, 35, 37, 38, 41, 67, and 68 are rejected under 35 U.S.C. 103 (a) as being unpatentable over US Patent No. 5,513,643 to Suite in view of US Patent No. 3,669,096 to Hurwitz. Suite teaches a blood pressure cuff assembly comprising an inflatable cuff member (sphygmomanometer cuff) configured to wrap about a body portion of a user. A resilient sleeve 10, 17 configured to reside under the wrapped cuff member, wherein the sleeve comprises at least one substantially axially extending rib support member 14, 16 or 20, 22, or 26a, b, wherein at least a major portion of the sleeve is configured to elastically expand to snugly and substantially conformably fit on a limb of a patient (see entire document, especially figs. 2-5; col. 2, line 31-col. 3, line 48 of Suite). The strips 14, 16 or 20, 22 are considered rib support members in that they are used to help support the sleeve on when in place on the user's arm and they are similar in shape to a rib in the human body. The reinforced edges 26a;b are considered rib support members in that they are formed by folding the edges of a material 24 over, such that elevated ridge or rib is formed (see col. 3, lines 37-41 of

Suite). Since the sleeve is made from a polyethylene material (see entire document, especially col. 2, lines 51-64 of Suite), which is elastic and capable of elastically expanding (see col. 2, lines 50-65 of US Patent No. 5,511,552 to Johnson for a teaching of a polyethylene material as being elastic and capable of elastically expanding) such that the elasticity would allow the sleeve to fit snugly and substantially conformably on a limb of a patient. Suite is silent as to the details of the cuff member.

However, Hurwitz teaches a sphygmomanometer cuff comprising an inflatable elongate cuff member having opposing long edges and opposing short edge portions with a fluid chamber 4 therein, and wherein, in operation, the short edge portions are configured to wrap around a body portion of a user and to connect to each other (see entire document, especially figs. 1- 5; col. 3, lines 13-39 and col. 3, line 54-col. 4, line 5 of Hurwitz). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the cuff member of Hurwitz as that of Suite, since Suite teaches using an inflatable cuff member and Hurwitz describes and appropriate such inflatable cuff member.

Regarding claim 35, the at least one rib support member 14, 16 or 20, 22 has an elongate flexible body configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 2, 4, and 5 of Suite).

Regarding claim 37, the at least one rib support member 14, 16 or 20, 22 is a plurality of laterally spaced apart rib support member configured to inhibit an upper edge

portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 1-5 of Suite).

Regarding claim 38, the sleeve remains unattached to the cuff member during operation (see entire document, especially col. 3, lines 21-49 of Suite).

Regarding claim 41, the sleeve includes opposing first and second short edge portions, wherein the first end portion is configured to releasably attach to the sleeve second end portion (see entire document, especially figs. 1-5; col. 3, lines 1-7 of Suite).

Regarding claim 67, the at least one rib is capable of projecting inwardly towards the skin of the limb of the patient inside the wrapped cuff, wherein the sleeve appears capable of being applied such that either the surface with rib 16, 20 or rib 14, 22 is facing towards the skin, or such that the folded edge 26a,b protrudes toward the skin. Furthermore, it appears that the pressure from the sphygmomanometer cuff during use would additionally cause the extra material of which the ribs are comprised to protrude towards the skin.

Regarding claim 68, the sleeve is configured to define a first closed member before the cuff member is wrapped over the sleeve and the cuff member defines a second closed member after the cuff member is wrapped over the sleeve (see entire document, especially fig. 5 of Suite).

Claim 54-58, 60, 63, 64, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,626,142 to Marks in view of Spence. Marks teaches an automated blood pressure monitoring system comprising a plurality of inflatable

blood pressure cuff assemblies, each sized and configured to accommodate a different patient size range and shown as having opposing long edges and opposing short edges and having an inflatable bladder or chamber therein. An inflation unit is in fluid communication with a selected blood pressure cuff and configured to generate a pressure sufficient to restrict blood flow in a selected artery of a patient, and means for releasing inflation pressure and detecting a signal corresponding to blood pressure measurements are also included (see entire document, especially fig. 1; col. 1, lines 20-64; col. 4, lines 37-49 of Marks). Marks is silent as to further details of the cuff assemblies.

However, Spence teaches an inflatable cuff assembly, usable for blood pressure measurements, comprising an inflatable elongate cuff member 13, 14 having opposing long edges and opposing short edge portions with an inflatable fluid chamber 12 therein (see entire document, especially figs. 2 & 4; col. 3, lines 19-32 of Spence). A resilient sleeve 15, 16 is attached to a respective one of the opposing short edge portions of the cuff member (see entire document, especially figs. 1, 3, & 4; col. 3, lines 41-46 of Spence). The sleeve comprises at least one substantially longitudinally extending rib support member 17, 42 and the rib is configured to inhibit the sleeve from rolling up and/or down the limb of the patient (see entire document, especially fig. 1; col. 3, line 54-col. 4, line 2 of Spence), wherein the stiffness provided by the stitching and the added material of strip 17 would serve to prevent such rolling at the edges of the sleeve. The sleeve's circumference may be adjusted to snugly fit the arm of a patient using strap 41 and strip 40 (see entire document, especially fig. 1; co. 3, lines 47-53 of

Spence) and the sleeve may be made of nylon (see entire document, especially col. 4, lines 1-4 of Spence), wherein nylon is an elastic fiber, such that the sleeve has a body sized and configured such that the sleeve is capable of expanding elastically to snugly and substantially conformably fit on a limb of the patient prior to inflation of the cuff member. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the blood pressure cuff assembly of Spence as that of Marks, since Marks teaches using a blood pressure cuff assembly and Spence describes an appropriate such assembly.

Regarding claims 55 and 56, the sleeves are fixedly attached to the corresponding cuff members (see entire document, especially figs. 3 & 4; col. 3, line 54-col. 4, line 2 of Spence). Regarding claim 56, the sleeves are releasably attached to the cuff members, wherein the sleeves may be released by undoing or destroying the stitches.

Regarding claim 57, one short edge portion is configured to be releasably attachable to the other opposing sleeve short edge portion to define a closed sleeve having an axially extending aperture, wherein the short edge portion is configured to be so attachable via its connection to the sleeve wherein the strip 40 and strap 41 are releasably attachable so as to define such a closed sleeve (see entire document, especially fig. 1 of Spence).

Regarding claim 58, the at least one rib support member has an elongate flexible body configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 1, 3, & 4 of Spence).

Regarding claim 60, the at least one rib support member is a plurality of laterally spaced apart rib support members configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 1, 3, & 4 of Spence).

Regarding claims 63 and 64, the assembly is configured for ambulatory or stress test blood pressure measurements (see entire entirety of Marks and Spence), wherein "ambulatory" and "stress test" are merely intended use language and the device is clearly capable of use by patients who are not bedridden or who are "ambulatory", or during a stress test.

Regarding claim 69, the at least one rib 17, 24 projects inwardly toward the skin of the limb of the patient, inside the wrapped cuff, when the sleeve and cuff are placed on the patient's arm (see entire document, especially figs. 1, 3 and 4 of Spence).

Claim 54-59, 63, 64, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,626,142 to Marks in view of Nagai, and further in view of Spence. Marks teaches an automated blood pressure monitoring system comprising a plurality of inflatable blood pressure cuff assemblies, each sized and configured to accommodate a different patient size range and shown as having opposing long edges and opposing short edges and having an inflatable bladder or chamber therein. An inflation unit is in fluid communication with a selected blood pressure cuff and configured to generate a pressure sufficient to restrict blood flow in a selected artery of a patient, and means for releasing inflation pressure and detecting a

signal corresponding to blood pressure measurements are also included (see entire document, especially fig. 1; col. 1, lines 20-64; col. 4, lines 37-49 of Marks). Marks is silent as to further details of the cuff assemblies.

However, Nagai teaches an inflatable blood pressure cuff assembly comprising an inflatable cuff member having an inflatable fluid chamber therein (inflatable bladder) and a resilient sleeve 14, 16, the sleeve comprising at least one substantially longitudinally extending rib support member 32, wherein the rib is configured to inhibit the sleeve from rolling up and/or down the limb of the patient (see entire document, especially figs. 1-3; col. 2, lines 1-19 and lines 52-64 of Nagai). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the assembly of Nagai in differing sizes and width as those of Marks, since Marks teaches a cuff assembly, and Nagai describes an appropriate such assembly. Marks, as modified, is silent as to the construction of the cuff member with respect to the sleeve and as to the material from which the sleeve is made

However, Spence teaches an inflatable tourniquet cuff assembly, wherein a tourniquet is known to be used for blood pressure measurement, comprising an inflatable elongate cuff member 13, 14 having opposing long edges and opposing short edge portions with an inflatable fluid chamber 12 therein (see entire document, especially figs. 2 & 4; col. 3, lines 19-32 of Spence). A resilient sleeve 15, 16 is attached to a respective one of the opposing short edge portions of the cuff member (see entire document, especially figs. 1, 3, & 4; col. 3, lines 41-46 of Spence). The sleeve's circumference may be adjusted to snugly fit the arm of a patient using strap 41

and strip 40 (see entire document, especially fig. 1; co. 3, lines 47-53 of Spence) and the sleeve may be made of nylon (see entire document, especially col. 4, lines 1-4 of Spence), wherein nylon is an elastic fiber, such that the sleeve has a body sized and configured such that the sleeve is capable of expanding elastically to snugly and substantially conformably fit on a limb of the patient prior to inflation of the cuff member. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the construction of the cuff member with respect to the sleeve of Spence as that of Marks, as modified, since Marks, as modified, teaches an inflatable cuff member within a sleeve, and Spence describes appropriate construction of such a cuff member within a sleeve. It would similarly have been obvious to one of ordinary skill in the art at the time of invention to use the material of the sleeve of Spence as that of Marks, since Marks, as modified teaches a pressure cuff having a sleeve, and Spence describes appropriate material for such a sleeve.

Regarding claims 55 and 56, the sleeves are fixedly attached to the corresponding cuff members (see entire document, especially figs. 3 & 4; col. 3, line 54-col. 4, line 2 of Spence). Regarding claim 56, the sleeves are releasably attached to the cuff members, wherein the sleeves may be released by undoing or destroying the stitches.

Regarding claim 57, one short edge portion is configured to be releasably attachable to the other opposing sleeve short edge portion to define a closed sleeve having an axially extending aperture, wherein the short edge portion is configured to be so attachable via its connection to the sleeve wherein the connecting portions 24 and 26

are releasably attachable so as to define such a closed sleeve (see entire document, especially figs. 1, 2, and 6 of Nagai).

Regarding claim 58, the at least one rib support member has an elongate flexible body configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 1 and 2 of Nagai).

Regarding claim 59, the sleeve comprises at least one rib channel 33 sized and configured to hold the at least one rib support member therein (see entire document, especially figs. 1 & 2; col. 2, lines 20-25 of Nagai).

Regarding claims 63 and 64, the assembly is configured for ambulatory or stress test blood pressure measurements (see entire entirety of Marks and Spence), wherein "ambulatory" and "stress test" are merely intended use language and the device is clearly capable of use by patients who are not bedridden or who are "ambulatory", or during a stress test.

Regarding claim 69, the at least one rib 17, 24 projects inwardly toward the skin of the limb of the patient, inside the wrapped cuff, when the sleeve and cuff are placed on the patient's arm (see entire document, especially figs. 1 & 2 of Nagai).

Claim 54, 58, 60-64, 69, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,626,142 to Marks in view of US Patent No. 5,513,643 to Suite. Marks teaches an automated blood pressure monitoring system comprising a plurality of inflatable blood pressure cuff assemblies, each sized and

configured to accommodate a different patient size range and shown as having opposing long edges and opposing short edges and having an inflatable bladder or chamber therein. An inflation unit is in fluid communication with a selected blood pressure cuff and configured to generate a pressure sufficient to restrict blood flow in a selected artery of a patient, and means for releasing inflation pressure and detecting a signal corresponding to blood pressure measurements are also included (see entire document, especially fig. 1; col. 1, lines 20-64; col. 4, lines 37-49 of Marks). Marks lacks each of the blood pressure cuff assemblies including a sleeve.

However, Suite teaches a sleeve to be used with a blood pressure cuff assembly. The sleeve 10, 17has a predetermined patient size range and is capable of being attached (attachable) to a respective one of the opposing short edge portions of the inflatable elongate cuff member. The sleeve 10, 17 comprises at least one substantially axially extending rib support member 14, 16 or 20, 22, or 26a, b, wherein at least a major portion of the sleeve is configured to elastically expand to snugly and substantially conformably fit on a limb of a patient (see entire document, especially figs. 2-5; col. 2, line 31-col. 3, line 48 of Suite). The strips 14, 16 or 20, 22 are considered rib support members in that they are used to help support the sleeve on when in place on the user's arm and they are similar in shape to a rib in the human body. The reinforced edges 26a,b are considered rib support members in that they are formed by folding the edges of a material 24 over, such that elevated ridge or rib is formed (see col. 3, lines 37-41 of Suite). Since the sleeve is made from a polyethylene material (see entire document, especially col. 2, lines 51-64 of Suite), which is elastic and capable of

elastically expanding (see col. 2, lines 50-65 of US Patent No. 5,511,552 to Johnson for a teaching of a polyethylene material as being elastic and capable of elastically expanding) such that the elasticity would allow the sleeve to fit snugly and substantially conformably on a limb of a patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sleeves of Suite with the system of Marks in order to eliminate the risk of contamination (see entire document, especially col. 2, lines 1-3 of Suite).

Regarding claim 58, the at least one rib support member 14, 16 or 20, 22 has an elongate flexible body configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 2, 4, and 5 of Suite).

Regarding claim 60, the at least one rib support member 14, 16 or 20, 22 is a plurality of laterally spaced apart rib support member configured to inhibit an upper edge portion of the sleeve from rolling down when in position on a user (see entire document, especially figs. 1-5 of Suite).

Regarding claims 61 and 62, since the sleeves are configured to be disposed of after each use (see entire document, especially col. 1, lines 54-58 of Suite), the combination of Marks with Suite would implies a kit of a number of sleeves, at least one per cuff assembly, per number of times each assembly is to be used. Further, the sleeves are fully capable or configured to be individually selectably releasably attachable to the blood pressure cuff members. Regarding claim 62, the sleeves are arranged in different predetermined sizes, wherein each sleeve should be of sufficient

width to be wider than the cuff of the sphygmomanometer with which it is used (see entire document, especially col. 2, lines 42-46 of Suite) and each sleeve is to be used with a cuff of differing width (see entire document, especially fig. 1 and col. 3, lines 23-29 of Marks).

Regarding claims 63 and 64, the assembly is configured for ambulatory or stress test blood pressure measurements (see entire entirety of Marks and Suite), wherein "ambulatory" and "stress test" are merely intended use language and the device is clearly capable of use by patients who are not bedridden or who are "ambulatory", or during a stress test.

Regarding claim 69, the at least one rib is capable of projecting inwardly towards the skin of the limb of the patient inside the wrapped cuff, wherein the sleeve appears capable of being applied such that either the surface with rib 16, 20 or rib 14, 22 is facing towards the skin, or such that the folded edge 26a,b protrudes toward the skin. Furthermore, it appears that the pressure from the sphygmomanometer cuff during use would additionally cause the extra material of which the ribs are comprised to protrude towards the skin.

Regarding claim 70, the sleeve is configured to define a first closed member before the cuff member is wrapped over the sleeve and the cuff member defines a second closed member after the cuff member is wrapped over the sleeve (see entire document, especially fig. 5 of Suite).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Although new grounds of rejection have been applied to claim 26, the applicants provided arguments with respect to the Spooner reference, which reference is still relied upon in the new grounds of rejection. The applicants have stated that the soft open weave of Spooner would not be able to help support a blood pressure cuff on a limb of a patient (see p. 15 of the arguments submitted 2/6/07). However, the material does appear capable of use in a sleeve for a blood pressure cuff member, as described above. Additionally, the applicants have provided no evidence of the inability of the material of Spooner to support any blood pressure cuff on a limb of a patient. The argument appears to be mere opinion on the part of the applicant, and, as such, is found unconvincing without evidence.

Allowable Subject Matter

Claims 21, 24, 25, and 28 are allowed. The allowability of these claims was addressed in the previous Office action, filed 11/14/06, and is repeated below.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 21, the prior art of record fails to teach or fairly suggest an inflatable blood pressure cuff assembly comprising a sleeve sensor chamber that has a lower edge portion that is seamless and has a lower edge portion that is open, in combination with all of the other limitations of the claim.

Regarding claims 24, 25, and 28, the prior art of record fails to teach or fairly suggest an inflatable blood pressure assembly comprising a sleeve that is attached to the inflatable elongate cuff member, has at least one rib support member, and comprises a curvilinear cable channel in communication with the sensor chamber, the cable channel including an intermediate segment that is arcuate, a lower first segment that is substantially longitudinal, and an upper segment above the arcuate segment that includes lateral directional components, in combination with all of the other limitations of the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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